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FACSIMILE COVER LETTER

To: Ebenezer Sackey
Patent Examiner

Firm: United States Patent and Trademark Office

Facsimile: (571) 273-8300

From: Howard C. Lee
Reg. Patent Agent

Date: August 4, 2005

Re: U.S. Patent Applin. Serial No. 10611,539
for "INHIBITORS OF CYCLIN DEPENDENT KINASES AND THEIR
USES"
Applicant(s): LAL et al.
Filed: 1 July 2003
FLH Ref. No.: 512425-2001.1

Number of Pages: 5
(including cover page)

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

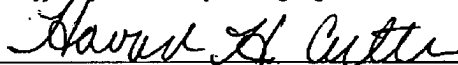
Applicants : LAL et al.
Serial No. : 10/611,539
Filing Date : 1 July 2003
For : **INHIBITORS OF CYCLIN DEPENDENT KINASES AND THEIR USES**
Examiner : Ebenezer Sackey
Art Unit : 1626

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Signature

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RESPONSE TO RESTRICTION REQUIREMENT

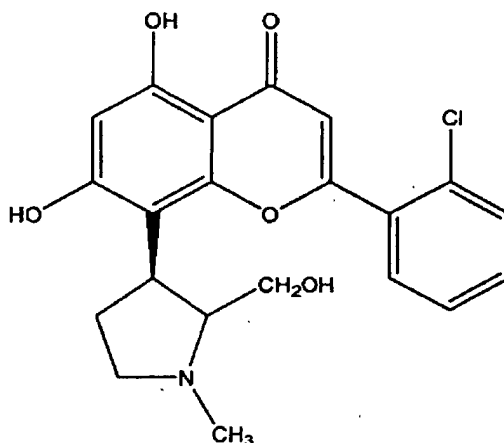
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

In response to the restriction and election of species requirement mailed on 5 July 2005, the invention of **Group I, claims 1-13** (drawn to compounds and pharmaceutical compositions, classified in Class 546, 548 and 514, in various subclasses) and **compound 12 ((+)-trans-2-(2-chlorophenyl)-5,7-dihydroxy-8-(2-hydroxymethyl-1-methyl-pyrrolidin-3-yl)-chromen-4-one** - see Example 11 on page 73 and Table 2 on page 147 of the specification) is elected, with **traverse**, for search purposes.

PATENT
512425-2001.1**I. PRELIMINARY NOTE**

compound 12 ((+)-*trans*-2-(2-chlorophenyl)-5,7-dihydroxy-8-(2-hydroxymethyl-1-methylpyrrolidin-3-yl)-chromen-4-one) has the structure:

**II. TRAVERSAL OF RESTRICTION**

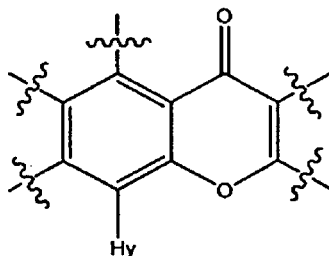
The applicants respectfully request reconsideration of the restriction and election of species requirements for the following reasons. MPEP 803 states that there are two requirements for restriction between patentably distinct inventions:

- (A) The inventions must be independent (see MPEP § 802.01, § 806.04, § 808.01) or distinct as claimed (see MPEP § 806.05 - § 806.05(i)); and
- (B) There must be a serious burden on the examiner if restriction is required (see MPEP § 803.02, § 806.04(a) - § 806.04(i), § 808.01(a), and § 808.02).

With regard to the compound claims (Group I), while the Examiner has explained which the inventions are independent or distinct as claimed, there has been no reasons given as to why the additional inventions would represent a serious burden on the office. The mere fact that a compound may be classified in different class and subclasses is not *prima facie* evidence that a search of the claims would constitute an undue burden as virtually all issued patents, especially those in the chemical arts, have several class and subclasses listed in the classification or in the field of search. As stated in MPEP 803: "If the search and examination of an entire application can be made without serious burden, *the examiner must examine it on the merits*, even though it includes claims to independent or distinct inventions." At the very least, the scope of the claims should be examined for the definition of A where the ring is 5- or 6-membered and the

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heteroatom is nitrogen as a structure search without undue burden be accomplished by using a core structure of:



with the parameters for Hy (heterocycle) being set for a range of the number of carbons being 4-5 and a range for the number of nitrogens being 1-2 (search query is for an STN/CAS structure search).

With regard to the method of use (Group II) and process (Groups III and IV) claims, since the Examiner agreed to rejoin the claims from these groups with the compound claims of Group I (presuming the compounds described in the claims of Groups II-IV are commensurate in scope with the compound claims of Group I), the applicants' arguments for traversal are effectively rendered moot.

However, in order to preserve the right to petition the finality of the restriction requirement, the applicants note for the record that their traversal was based on the fact that the claims of Groups II-IV are all ultimately dependent upon claim 1, i.e. each of the Groups of claims are linked together.

MPEP 809.03 (Linking Claims) states in part that "[t]he most common types of linking claims which, if allowed, act to prevent restriction between inventions that can otherwise be shown to be divisible, are

- (A) genus claims linking species claims;
- (B) a claim to the necessary process of making a product linking proper process and product claims;
- (C) a claim to "means" for practicing a process linking proper apparatus and process claims; and
- (D) a claim to the product linking a process of making and a use (process of using)."

Type (D) most closely resembles the relationship between the claims of the invention. As such, the Examiner is reminded that MPEP 809 states in part that "[t]he

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linking claims must be examined with the invention elected, and should any linking claim be allowed, the restriction requirement must be withdrawn." (emphasis added)

For any of the above reasons, the restriction requirement and the election of species requirement can properly be withdrawn.

Should the restriction/election of species be made final, the applicants reserve their right to petition the Group Director regarding the finality of the restriction/election of species. Favorable action is earnestly solicited.

Respectfully submitted,

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